UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,135	05/31/2001	Brandon James Yoe	50623.00168	1923

7590 08/15/2003

CAMERON KERRIGAN
SQUIRE,SANDERS & DEMPSEY L.L.P
ONE MARITIME PLAZA, SUITE 300
SAN FRANCISCO,, CA 94111-3492

EXAMINER
NGUYEN, CAMTU TRAN

ART UNIT	PAPER NUMBER
3749	15

DATE MAILED: 08/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,135	Applicant(s) YOE ET AL.	
	Examiner Camtu T. Nguyen	Art Unit 3749	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,10-32,37-39,41-44 and 46-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,10-32,37-39,41-44 and 46-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment filed on May 6, 2003. Claims 4, 8, 9, 33-36, 40, and 45 have been cancelled without prejudice. Claims 46-72 are newly added claims such that claims 1-3, 5-7, 10-32, 37-39, 41-44, and 46-72 are pending. Applicant's comments pertaining to the Turnlund et al Publication (US 2001/0001806 A) are acknowledged but are not persuasive. Turnlund et al Publication disclose in paragraph [0056] that the stent may be configured to irradiate different levels of radiation longitudinally and/or circumferentially along the stent and as such, the stent undergoes the changes in the value of quantity such as concentrations along the stent longitudinally and/or circumferentially. The claims, as amended, have been carefully considered and are rejected for the reasons follow herein below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 7, 10-16, 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al (U.S. Patent No. 5,782,742). Crocker et al disclose a medical device positioning

at a treatment site in a vessel and having an inflatable balloon having a radiation carrier such as a radiation delivery layer thereon. Figures 3 and 4 illustrate the radioactive balloon (18) comprises a proximal zone (28), a distal zone (30), and a central zone (32) wherein the central zone (32) comprises a balloon wall (36) surrounded by radiation source (34), therefore, the radioactive balloon (18) has gradients of concentrations along the length of the balloon. Crocker et al teach that the radiation source (34) comprises a metal foil such as gold preferably distributing evenly circumferentially around the balloon (18). The device is capable of carrying out the steps recited in the method claims such as forming the radioactive region, the distal end region, the proximal end on the delivery source, and having the delivery source delivering a therapeutic agent level of radioactivity between the proximal and distal ends.

Claims 21-32, 46-48, 50-55, 57-60, 62, 63, and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Turnlund et al (Publication No. US2001/0001806A1). Turnlund et al discloses in Figures 3 and 5 a conventional stent-graft delivery system (28) comprising an expandable radioisotope stent-graft (23) with a deformable, tubular stent (20) mounted onto the balloon (31) at the distal portion of the stent-graft delivery system (28). Turnlund teaches preferably radioisotopes include alpha, beta, or low energy gamma emitters with the endovascular radiation dose ranges from about 1 Gy to about 600 Gy. The stent-graft (23) constructed to deliver a dose of endovascular radiation upon the selected region (21) and the anatomy of the stent (25) include the central region (38), the proximal portion (41), and the distal portion (40) and Turnlund further teaches that stent-graft (23) having an uniform radioactivity longitudinally therealong will not emit at a uniform rate of radiation near the proximal and distal portions (41, 40), as compared to the center region (38) of the stent graft, thereby, Turnlund et al

appreciates the radiation dosages should not be as high at the proximal and distal portions (41, 40). Figure 6 illustrates a graphical chart illustrating the Dose to Tissue vs. Distance From the Surface of Stent. In particular, Chart 1 graphs the changes of dose along the length of the stent, decreasing from the central region (38) toward an end of the stent, thus, displaying the stent is configured to irradiate different levels of radiation longitudinally along the stent, thereby, yielding changes in concentrations along the stent longitudinally and/or circumferentially (paragraphs [0031], [0036], [0037], [0045], [0048], [049], [0051], [0052], [0056-0061]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker et al (U.S. Patent No. 5,782,742) in view of Turnlund et al (Publication No. US2001/0001806A1). Crocker et al disclose in Figure 1 a radiation delivery catheter (10) embodying addition features know in the vascular dilation art, such as carrying an implantable stents, drug delivery, perfusions, and dilation features, or any combination of these features, can be used in combination with the balloon. Turnlund et al disclose an expandable radioisotope stent-graft (23) with a deformable, tubular stent (20) mounted onto the balloon (31) at the distal portion of the stent-graft delivery system (28). Therefore, it would have been obvious to one ordinary skill

in the art to combine the stent taught by Turnlund et al as Crocker et al's catheter is equipment to receive a stent.

Claims 17, 18, 49, 56, 61, 64, 68, and 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker et al (U.S. Patent No. 5,782,742) in view of Tang et al (U.S. Patent No. 6,504,232). Crocker et al disclose a medical device positioning at a treatment site in a vessel and having an inflatable balloon having a radiation carrier such as a radiation delivery layer thereon but do not teach the radioactive region comprises a coating with isotopes by ion beam implantation, as recited. Tung et al teach the radioisotopes may be imprinted on the surfaces of the stent by various methods known in the art (column 4 lines 23-43). Therefore it would have been obvious to one of ordinary skill in the art to coat Crocker et al's medical device using Tung et al's ion beam implantation method. As regards the method claims, Crocker et al's device, as modified, is capable of performing the steps particularly to form a coat on a stent and to apply a drug such that the central region comprises a drug, wherein the distal region and the proximal region are free from any drug. As regards the proximal and the distal ends having less drug that than of the central region, one of ordinary skill in the art would have coated the stent at those ends with such gradual gradients from a distal or proximal region to the central region as such would avoid any potential vessel injury.

Claims 19, 20, 49, 56, 61, 64, 68, and 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker et al (U.S. Patent No. 5,782,742) in view of Malik et al (U.S. Patent No. 6,504,307). Crocker et al disclose a medical device positioning at a treatment site in a vessel and having an inflatable balloon having a radiation carrier such as a radiation delivery layer thereon but do not teach the radioactive region comprises a coating with isotopes by plasma

implantation, as recited. Malik et al teach an apparatus and method for modifying a surface of a target relating such as ionizing plasmas and generally to the manufacture of medical devices such as stents or catheter for implantation within the body of a patient. Therefore it would have been obvious to one of ordinary skill in the art to utilize the plasma ion implantation suggested by Malik et al for coating the Crocker et al's delivery source as such would be beneficial and advantageous because plasma ion implantation provides uniform ion dose and also do not leach out, wash or become part of the blood stream. As regards the method claims, Crocker et al's device, as modified, is capable of performing the steps particularly to form a coat on a stent and to apply a drug such that the central region comprises a drug, wherein the distal region and the proximal region are free from any drug. As regards the proximal and the distal ends having less drug that than of the central region, one of ordinary skill in the art would have coated the stent at those ends with such gradual gradients from a distal or proximal region to the central region as such would avoid any potential vessel injury.

Claims 41-44, 49, 56, 61, 64, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker et al (U.S. Patent No. 5,782,742) in view of Segal (U.S. Patent No. 6,059,752). Crocker et al disclose a medical device positioning at a treatment site in a vessel and having an inflatable balloon having a radiation carrier such as a radiation delivery layer thereon but do not teach the radioactive region comprises dipping and coating in the drug, as recited. Segal discloses in Figure 8 a irradiation device (81) comprising an intermediate portion (86a), proximal and distal extremities (87, 88), of which the intermediate portion (86a) is covered or coated and encapsulated with radially expandable and contracting material (91) such as a latex, polyurethane, silicone, or other thermoplastic elastomer, and masking off the extremities (87, 88)

by a masking material and then dipping into a desired coating material and then cured in an appropriate manner. Therefore it would have been obvious to one of ordinary skill in the art to coat Crocker et al's medical device suggested by Segal as such coating would protect vessel wall from damage and prevent potential entrapment (column 8 lines 15-67, column 9 lines 1-10).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 703-305-0537. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on 703-308-1935. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Camtu Nguyen
August 7, 2003

Ira S. Lazarus
Supervisory Patent Examiner
Group 3700